UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
NORTHERN DIVISION

GENBIOPRO, INC. **PLAINTIFF**

V. **C.A. NO. 3:20-CV-00652-HTW-LRA**

DR. THOMAS DOBBS, STATE HEALTH OFFICER OF THE MISSISSIPPI DEPARTMENT OF HEALTH, IN HIS OFFICIAL CAPACITY **DEFENDANTS**

PLAINTIFF GENBIOPRO, INC.'S BRIEF IN SUPPORT OF ITS RESPONSE IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

INTRODUCTION

As Plaintiff stated in its Response in Opposition to Defendant's Motion to Dismiss, Defendant Dr. Thomas Dobbs, State Health Officer of the Mississippi Department of Health, seeks to dismiss the Complaint on the ground that Plaintiff GenBioPro ("GBP") lacks standing because it failed to allege an injury-in-fact traceable to Mississippi's restrictions on the use and sale of GBP's product. Defendant further alleges that the Complaint must be dismissed because GBP has failed to state a claim for conflict preemption or under the dormant Commerce Clause. But this is simply a refusal to accept, as the Court must on a motion to dismiss, that the actual allegations in the Complaint meet the well-established legal requirements for standing and to state a claim for implied preemption and dormant Commerce Clause. GBP pleaded in its Complaint that (1) GBP is the only company in the United States approved by the FDA to market and sell the generic version of the prescription drug mifepristone, an FDA-approved medication; (2) Congress granted the FDA the exclusive authority to regulate GBP's product under a detailed and thorough statutory scheme, which FDA has done, that balances the public health benefits of the medication with its risks; (3) Mississippi enacted restrictions that conflict with the FDA's carefully constructed

balance and frustrate the purpose of the federal regulatory scheme; and (4) Mississippi's draconian restrictions have severely curtailed the sale and use of GBP's product within the state of Mississippi, causing financial harm to GBP. Nothing more is required at this stage. Because GBP plainly alleges that Mississippi's regulatory scheme conflicts with the FDA's regulatory scheme and frustrates its purpose, and that Mississippi's restrictions have caused and will continue to cause GBP to lose sales, the motion to dismiss must be denied.

Defendant spends the majority of his efforts arguing, without legal support, that an abortion-inducing prescription medication is somehow "different" from the other 20,000 medications regulated by the FDA, and that this supposed difference justifies Mississippi's decision to impose conflicting restrictions on the use and sale of the FDA-approved medication. Defendant can cite no legal authority for this argument. Indeed, the Supremacy Clause was designed to prevent exactly the regulatory mayhem that would result from Defendant's position: 50 states deciding for themselves which FDA-approved drugs are somehow "special" or "different" and thereby overruling Congress's desire for a uniform scheme. Such an exception would render preemption a hollow doctrine.

For the reasons set forth below, GBP's standing and claims have been adequately pleaded and Defendant's Motion to Dismiss should be denied.

ARGUMENT

I. GBP'S PLEADED ECONOMIC INJURY CLEARLY ESTABLISHES FIRST-PARTY STANDING AND IS NEITHER SPECULATIVE NOR ATTENUATED

Defendant claims that GBP, which markets and sells generic mifepristone, lacks standing to challenge Mississippi's restrictions on the use and sale of GBP's product within the state. Defendant argues that GBP's allegations – that these severe restrictions cause GBP economic harm

– somehow do not establish a legally-cognizable injury and GBP's continuing lost sales are not causally related to Mississippi's excessive restrictions on the use and sale of GBP's product.

The requirements for Article III standing are well-settled: a plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). GBP has pleaded the following allegations in detail: (1) GBP sells a product, generic mifepristone, approved by the FDA for nationwide marketing and use subject to strict FDA regulations (Compl. ¶¶ 11, 35) and Mississippi unlawfully restricts the sale and use of mifepristone, beyond the standards set by the FDA, creating an ongoing economic injury to GBP in the form of lost sales and lost revenue (Compl. ¶ 75); (2) Mississippi's challenged laws restrict the ability of healthcare providers to prescribe GBP's product, causing GBP to lose sales, revenue, and the opportunity to market and sell its product in Mississippi (Compl. ¶¶ 66-76); and (3) a ruling that Mississippi's state law restrictions conflict with and frustrate the purpose of Congress's intent in granting the FDA authority to approve drugs for safe use, including determining the appropriate balance between any conditions required to ensure safe use and patient access, would be redressed by a favorable decision in this case (Compl. ¶ 87). These allegations, as pleaded, are more than adequate to establish first-party standing.

A. Defendant Misstates the Applicable Standard of Review

Defendant's standing arguments are premised on the (incorrect) notion that this Court need not accept GBP's pleaded facts as true, suggesting that "no presumptive truthfulness attaches" to GBP's allegations establishing standing. Def's. Mem. at 11. Defendant suggests that the Court can, and should, "decide disputed issues of material fact in order to determine" if it has jurisdiction. *Id.* (citing *Montez v. Department of the Navy*, 392 F.3d 147 (5th Cir. 2004) and *Williamson v.*

Tucker, 645 F.2d 404 (5th Cir. 1981)). But, not surprisingly, that standard applies only when Defendant submits that there are disputed facts, beyond the scope of the pleadings, material to the standing analysis. Here, Defendant has presented no facts – disputed or otherwise – to the Court. Defendant has thus made what is known as a facial, rather than factual, attack on jurisdiction. *See Braatz, L.L.C. v. Red Mango FC, L.C.C.*, 642 F. App'x 406, 409 (5th Cir. 2016) (an attack is facial when Defendant does "not file[] any supporting affidavits, testimony, or other evidentiary materials"); *Paterson v. Weinberger*, 644 F.2d 521, 523 (5th Cir. 1981) ("If the defense merely files a Rule 12(b)(1) motion, the trial court is required merely to look to the sufficiency of the allegations in the complaint because they are presumed to be true . . . If a defendant makes a "factual attack" upon the court's subject matter jurisdiction over the lawsuit, the defendant submits affidavits, testimony, or other evidentiary materials.").

When resolving a facial attack, as this one, GBP's standing allegations must be taken as true for purposes of deciding this motion. *See Braatz*, 642 F. App'x. at 409 (5th Cir. 2016) (in a facial attack, a court must "presume the allegations in the complaint are true and determine whether the complaint is sufficient to allege the jurisdiction") (internal citations omitted); *see also Williamson*, 645 F.2d at 412 (finding that where a defendant challenges jurisdiction on the face of the complaint, "the plaintiff is left with safeguards similar to those retained when a Rule 12(b)(6) motion to dismiss for failure to state a claim is raised–the court must consider the allegations in the plaintiff's complaint as true"). Thus, this Court must "presume" that GBP's allegations "embrace those specific facts that are necessary to support the claim," *Lujan*, 504 U.S. at 561, and Defendant's motion to dismiss for lack of subject matter jurisdiction should be granted "only if it appears *certain* that the plaintiff cannot prove *any* set of facts in support of his claim that would

entitle him to relief," *Home Builders Ass'n of Miss., Inc. v. City of Madison*, 143 F.3d 1006, 1010 (5th Cir. 1998) (emphasis supplied).

B. GBP's Detailed Factual Allegations Are More than Sufficient to Show that It Is Entitled to Relief

1. The current and ongoing economic injury GBP has pleaded is a paradigmatic injury-in-fact.

GBP has pleaded that Mississippi's onerous restrictions, which conflict with FDA approval for its product and burden interstate commerce, have caused and will continue to cause financial harm, "a classic and paradigmatic form of injury in fact." *Maryland Shall Issue, Inc. v. Hogan*, 971 F.3d 199, 210 (4th Cir. 2020) ("the operation of a challenged statute that results in the constriction of a vendor's buyers' market plainly inflicts an injury in fact sufficient to guarantee it concrete adverseness") (internal punctuation omitted); *see also Danvers Motor Co. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir. 2005) ("While it is difficult to reduce injury-in-fact to a simple formula, economic injury is one of its paradigmatic forms."); *San Diego County Gun Rights Comm. v. Reno*, 98 F.3d 1121, 1130 (9th Cir. 1996) ("Economic injury is clearly a sufficient basis for standing."); Wright and Miller, Federal Practice and Procedure, § 3531.4 at 830 (2005 Supp.) ("Standing is found readily, particularly when injury to some traditional form of property is asserted.").

In order to argue a lack of standing, Defendant's Motion cites several opinions from cases where the only pleaded harm was a "threatened future injury." But GBP did not plead "threatened future injury." Rather, GBP has pleaded an actual and ongoing economic harm that is neither

solely a threatened future injury nor highly speculative.[1] Defendant cherry-picks just one phrase in GBP's Complaint – that GBP "stands to suffer substantial lost sales in Mississippi" – to manufacture its argument that GBP's pleaded injury is "not an actual injury" and "only conjecture." Def's. Mem. at 13. To realize the inaccuracy of this argument, the Court need only read the adjacent paragraphs of GBP's Complaint, setting forth allegations of economic injury that are more than adequate to establish an injury-in-fact. Compl. ¶¶ 66-76 ("Imposition of unconstitutional state law restrictions on the prescription and use of mifepristone causes, and will continue to cause, significant revenue loss to GBP."). Given that Defendant's motion is not accompanied by any facts to the contrary, the Court must accept GBP's allegations of current and continuing economic harm as true at this stage in the litigation. *Williamson*, 645 F.2d at 412.[2]

[1] GBP's injury is easily distinguished from the cases to which Defendant cites. *C.f. Stringer v. Whitley*, 942 F.3d 715, 720, 722 (5th Cir. 2019) (citations omitted) (plaintiffs whose voter registration was impeded because they moved to a new county had not alleged "substantial risk" of future injury because plaintiffs did not allege "any intention to move in the future"); *Prestage Farms v. Bd. of Sup's of Noxubee Cty.*, 205 F.3d 265, 266, 268 (5th Cir. 2000) (plaintiff, a hog producer, lacked standing to challenge a local county ordinance absent proof that ordinance would restrict his current operations; that the ordinance might restrict future expansion was too conjectural and hypothetical given that plaintiff did not allege plans to expand); *Little v. KPMG LLP*, 575 F.3d 533, 540–41 (5th Cir. 2009) (competitors of KPMG – which was not properly licensed and registered in Texas – lacked standing because their claimed lost business depended on numerous independent decisions by third parties – including that KPMG would not remedy its registration status and its displaced customers would then choose to hire plaintiffs instead – an injury "too speculative to confer Article III standing").

[2] Not only does Mississippi severely restrict the use and sale of mifepristone by throttling the number of prescribers and facilities that may dispense mifepristone (and thereby GBP's sales), it also restricts others (which would, presumably, include GBP) from "enabling" a non-physician healthcare professional licensed to prescribe FDA-approved medications to provide or administer mifepristone. *See* Miss. Code Ann. § 41-41-107. A violation of the Women's Health Defense Act is a punishable misdemeanor offense. *Id.* § 41-41-111.

2. GBP's economic injury is directly tied to Mississippi's onerous restrictions on the use and sale of its product.

Defendant also argues that, because Mississippi's laws restricting use of mifepristone regulate healthcare providers and not drug manufacturers such as GBP, there is no "traceable connection" between Mississippi's restrictions on the product and GBP's lost sales. Def's. Mem. at 13. But an injury is "traceable" as long as there exists "a causal connection between the injury and the conduct complained of." *Lujan*, 504 U.S. at 560. Defendant's conduct "need not be the last link in the causal chain" to be traceable to GBP's injury. *Maryland Shall Issue, Inc.*, 971 F.3d at 212 (internal punctuation omitted); *see also Environment Texas Citizen Lobby, Inc. v. ExxonMobil Corp.*, 968 F.3d 357, 368 (5th Cir. 2020) (explaining that "traceability requires something more than conjecture . . . but less than certainty.").

Here, as with its injury-in-fact, the adequacy of GBP's allegations is clear: Mississippi imposes burdensome restrictions on the use and sale of GBP's FDA-approved product, including severe restrictions on the healthcare providers who may prescribe the medication and the facilities in which it may be dispensed, that hamper GBP's ability to sell or promote its product in Mississippi. Compl. ¶¶ 67, 73-75. These restrictions cause GBP to lose sales and revenue. Compl. ¶¶ 73-75. Faced with the same injury and causation alleged here, other courts have held that traceability is obvious. *Zogenix, Inc. v. Patrick*, No. CIV.A. 14-11689-RWZ, 2014 WL 4273251, at *2 (D. Mass. Aug. 28, 2014) ("The economic injury [drug manufacturer] alleges is directly tied to the [challenged state] regulations; in other words, the burdens the regulations impose on prescribers lead them to write fewer prescriptions, which impacts plaintiff's bottom line.").

As a direct result of these restrictions, only one clinic in the entire state of Mississippi even meets the state's requirements for prescribing mifepristone. Compl. ¶ 69. But the limited number of facilities and providers who are able to prescribe mifepristone in Mississippi is not a comment

on the demand for mifepristone; rather it is a comment on the extent to which Mississippi's restrictions restrict access to mifepristone: even though the FDA prohibits the online sale of mifepristone (Compl. ¶ 71), a recently published, peer-reviewed analysis of online requests for mifepristone indicates that the demand for online sale of mifepristone across the United States is highest in Mississippi. Compl. ¶¶ 70-72 (citing A.R.A. Aiken et al., Demand for self-managed medication abortion through an online telemedicine Service in the United States. 110 Am. J. Public Health 1, 90–97 (2020), available at https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2019.305369 (last accessed Nov. 12, 2020)). GBP's Complaint alleges, and Dr. Aiken's research recently published in the *American Journal of Public Health* shows, that women are responding to these severe restrictions by turning to these illegal online sources to meet the demand for this medication, a demand that would otherwise result in increased sales for GBP. Compl. ¶¶ 70, 72-73.

3. A ruling that Mississippi's restrictions for mifepristone are preempted would redress GBP's ongoing economic injury.

The third and final element of standing – that a ruling prohibiting the challenged conduct would provide relief for Plaintiff's claimed injury – is also clearly satisfied here. S*ee Stringer*, 942 F.3d at 720 (holding that "plaintiffs seeking injunctive and declaratory relief can satisfy the redressability requirement only by demonstrating a continuing injury or threatened future injury"). Under the current FDA label and Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone, many more healthcare providers and facilities would be permitted to prescribe and dispense the medication than are currently allowed under Mississippi's conflicting laws – which would naturally lead to more sales. A ruling that Mississippi's draconian restrictions on the use of mifepristone are preempted would allow the use and sale of mifepristone subject to the current

FDA approval, resulting in increased access to, prescriptions for, and sales of GBP's product within the state and increased revenue for GBP.

II. GBP HAS THIRD-PARTY STANDING TO CHALLENGE THE MISSISSIPPI REGULATIONS ON BEHALF OF PRESCRIBERS AND WOMEN WHO SEEK TO USE MIFEPRISTONE

GBP's financial injury is paradigmatic first-party injury. But, alternatively, even if this Court were to find that GBP lacks first-party standing, GBP also has third-party standing on behalf of its customers, in this case the would-be providers of mifepristone and women seeking to use the medication.

The Supreme Court has made clear that the vendor-customer relationship, such as the relationship GBP has with the certified providers who prescribe its product and the women who are currently prevented from obtaining mifepristone in Mississippi, is sufficiently close to warrant third-party standing. *See Craig v. Boren*, 429 U.S. 190, 195 (1976) (holding that "vendors and those in like positions have been uniformly permitted to resist efforts at restricting their operations by acting as advocates of the rights of third parties who seek access to their market or function"); *see also Carey v. Population Services, Intern.*, 431 U.S. 678, 682–683 (1977) (finding that a corporation "engaged in the mail-order retail sale of nonmedical contraceptive devices" had standing to challenge state statute prohibiting distribution of contraceptives to minors and banning advertisement of contraceptives, "not only in its own right but also on behalf of its potential customers").

Defendant in fact acknowledges that a litigant may assert the rights of third parties when (1) the litigant has a close relationship to the third party and (2) there exists "some hindrance to the third party's ability to protect his or her own interests." *Powers v. Ohio*, 499 U.S. 400, 411 (1990). But Defendant mischaracterizes the nature of the requisite "close" relationship, claiming, without providing support for the assertion, that GBP must have a "confidential relationship" with

the providers and women who seek access to mifepristone. Def's. Mem. at 15. This is an overstatement of the requirements for third-party standing – GBP need only have close relationship with the consumers who seek the access they are due to GBP's product, which in this instance are both the healthcare providers who otherwise would be permitted to prescribe the product[3] and the women who ultimately take the medication. In any event, as GBP pleaded, GBP *does* have a confidential relationship with both the prescribers and end users of its product: under the FDA labeling and REMS, GBP is required to put processes in place to ensure and maintain secure and confidential information, including records of all transactions, shipments, and safety data. Compl. ¶ 38, Compl. Exhibit A.

GBP "is entitled to assert those concomitant rights of third parties that would be 'diluted or adversely affected' should [GBP's] constitutional challenge fail." *Carey*, 431 U.S. at 684 (quoting *Craig*, 429 U.S. at 195). It is well-settled that abortion rights litigation is of a sensitive nature, and that women seeking access to an abortion are hindered in their ability to protect their own interests. *See, e.g., Singleton v. Wulff*, 428 U.S. 106, 117 (1976) ("For one thing, [an individual woman] may be chilled from such assertion by a desire to protect the very privacy of her decision [for an abortion] from the publicity of a court suit. A second obstacle is the imminent

[3] Only a Certified Prescriber, as required under the current FDA labeling and REMS, may prescribe mifepristone. Compl. ¶¶ 43, 52. A healthcare provider may become a Certified Prescriber by providing GBP with a Prescriber Agreement Form attesting that he or she meets the FDA's qualifications for prescribing the medication. Compl. ¶ 37. GBP is responsible for ensuring that mifepristone is not distributed to non-certified clinics or healthcare providers, and that all Certified Prescriber requirements are met. Compl. Exhibit B at pg. 4. Certified Prescribers have specific obligations under the REMS, including obtaining a signed Patient Agreement Form before dispensing mifepristone, providing the patient with a copy, and placing a copy of the signed agreement in the patient's chart. Compl. ¶ 37.

mootness, at least in the technical sense, of any individual woman's claim.").[4] For these reasons, GBP's vendor-customer relationships plainly afford GBP third-party standing to assert its preemption claim.[5]

III. GENBIOPRO HAS ADEQUATELY STATED ITS CLAIMS

Defendant argues that both GBP's preemption and Dormant Commerce Clause claims should be dismissed for failure to state a claim, but these arguments fall as easily as Defendant's standing challenges do. In ruling on Defendant's 12(b)(6) challenges, this Court "must accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus*, 551 U.S. 89, 94 (2007). Dismissals for failure to state a claim "are viewed with disfavor and are rarely granted." *Test Masters Educ. Servs., Inc. v. Singh*, 428 F.3d 559, 570 (5th Cir. 2005). Dismissal is only proper where "the plaintiff cannot prove any set of facts that would entitle it to the relief it seeks" when all factual allegations are taken as true. *Id.*

[4] Without providing any basis for the assertion, Defendant seems to encourage this Court to disregard *Singleton v. Wulff*, 428 U.S. 106 (1976), because the ruling "has been . . . controversial." Def's. Mem. at 14. In *Singleton*, the Supreme Court held that abortion providers had standing to challenge a state statute limiting Medicaid coverage for abortions. The Court held that "[t]he closeness of the relationship is patent . . . A woman cannot safely secure an abortion without the aid of a physician, and an impecunious woman cannot easily secure an abortion without the physician's being paid by the State. The woman's exercise of her right to an abortion, whatever its dimension, is therefore necessarily at stake here." *Id*. at 117. Defendant's only support for the notion that *Singleton* is "controversial" is that the State of Mississippi currently has a petition for certiorari pending before the Supreme Court on a similar question. But the Supreme Court was recently presented with this same question in *June Medical Services, LLC, v. Russo*, 591 U.S. —, 140 S. Ct. 2103, 2118 (2020), and found that the State of Louisiana had waived its right to challenge standing. Defendant cannot ask this Court to dismiss settled precedent simply because Defendant personally views *Singleton* to be "controversial."

[5] Defendant also implies that because the name-brand manufacturer of mifepristone has not challenged Mississippi's restrictions, GBP somehow lacks standing to do so. Another entity's inaction in no way impacts GBP's ability to challenge Mississippi's unconstitutional regulations.

A. There Is No "Abortion Exception" to the Well-Settled Rules of Preemption.

This is a straightforward federal preemption case, which will turn on the question of whether state regulation impermissibly conflicts with decisions made by a federal agency, under powers delegated to it by Congress. Defendant, however, raises multiple red herrings by suggesting – inaccurately – that GBP's requested relief would somehow "nullify" the state's ability to regulate abortions and that Mississippi would lose its ability to license healthcare providers, safeguard patient health, maintain medical standards, and provide informed consent. But this parade of speculation has no basis in reality. Mississippi's ability to regulate abortion procedures, in keeping with the police powers of the states, would remain untouched. GenBioPro only seeks to remove those state law restrictions that conflict with the FDA approval of its product and thereby restrict the use and sale of its product in Mississippi.

Defendant also argues that GBP's case is somehow "different" than a "garden variety" preemption case, again because the FDA-approved drug at issue is for medicated abortion. But this argument carries no weight, and Defendant can provide no legal basis for an "abortion exception" to the rules of preemption.[6] The issue that this Court will ultimately be called on to decide for preemption purpose is whether state law conflicts with federal law (Mississippi *concedes* that its regulations of mifepristone do, Def's. Mem. at 20) and whether that conflict

[6] Although the Defendant says that from 1960 to 2006, "the states, not the FDA, were responsible for ensuring the health and safety of their citizens," Def's. Mem. at 10, the case it cites for this proposition, *Riegel v. Medtronic, Inc*., concerns medical devices, not prescription drugs. In fact, what *Medtronic* actually says is that the FDA only recently began regulating *medical devices,* and that it has long regulated drugs: "The Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended, 21 U.S.C. § 301 et seq., has long required FDA approval for the introduction of new drugs into the market. Until the statutory enactment at issue here, however, the introduction of new medical devices was left largely for the States to supervise as they saw fit." *Riegel v. Medtronic, Inc*., 522 U.S. 312, 315 (2008).

makes it impossible to comply with both or stands as an obstacle to Congressional intent (which Mississippi's restrictions clearly do).

Defendant's motion spills much ink about the state's interest in regulating abortion *procedures*, Def's. Mem. at 4-5, but the cases Defendant cites about a state's ability to regulate medical and surgical procedures are inapposite in this straightforward preemption case. Surgical abortions are not subject to FDA (or any other federal) oversight, so of course states should have the power to regulate those procedures, just as states have the power to regulate all sorts of things that doctors and other health professionals can and cannot do. This case is not challenging Mississippi's ability to regulate medical procedures, which has traditionally been within each state's police powers.

This case is, actually, exactly what Defendant claims it is not: a garden variety preemption case about the safe distribution and marketing of an FDA-approved medication obstructed by state laws that conflict with that FDA approval.

B. GenBioPro Sufficiently Pleaded a Valid Preemption Claim

GBP has set forth detailed factual allegations to support its preemption claim far beyond a "threadbare recital of the elements of a cause of action, supported by mere conclusory statements." *Patrick v. Wal-Mart, Inc.*, 681 F.3d 614, 622 (5th Cir. 2012) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Even though GBP "need only give the defendant fair notice of what the claim is and the grounds upon which is rests," *Erickson*, 551 U.S. at 93, GBP has provided specific and detailed allegations – including about the federal labeling and risk mitigation strategies for its FDA-approved product, Mississippi's conflicting state laws, how those laws frustrate the purpose of the FDA's approval of mifepristone, and the ongoing effect that those laws have on GBP's ability to sell its product in Mississippi.

In perhaps the best illustration that GBP has adequately pleaded its preemption claim, the Defendant was able to articulate a basis for GBP's claim quite well: obstacle preemption. GBP has alleged the required elements of obstacle preemption as follows: (i) a state law that conflicts with federal law (Compl. ¶¶ 1, 53-65); (ii) this conflict frustrates the purpose of the federal law (Compl. ¶¶ 66-72); and (iii) GBP has suffered a plausible and actual injury: current and ongoing economic harm from the state law restrictions on the sale of its product (Compl. ¶¶ 73-76). These facts, as pleaded by GBP, must be accepted as true at this stage and are sufficient to overcome Defendant's 12(b)(6) challenge. *Erickson*, 551 U.S. at 94.

What's more, Defendant actually *admits* that Mississippi's laws conflict with the current FDA labeling and REMS: "Mississippi law supplies some additional safeguards still deemed prudent by the State, but which the FDA saw fit to relax." Def's. Mem. at 20. Though Mississippi greatly downplays the extent of the conflict between its laws and the FDA's current REMS for mifepristone,[7] they admit that a conflict does exist here between state and federal law.

Defendant acknowledges, as he must, that claims for federal preemption can be made whenever the challenged state action would serve as an obstacle to Congress's purpose. And as described above, there can be no doubt that GBP has pleaded the necessary elements to state such

[7] To be clear – Mississippi's restrictions on the use and sale of mifepristone are not "*de minimis*" restrictions that "vary in the slightest degree," as Defendant misleadingly suggests throughout the motion. Def's. Mem. at 2, 22. Defendant says that the 2013 Act just "mirrored" the original REMS before some restrictions relaxed in 2016, but one of the most problematic aspects of the state's restrictions is that it defines abortion, generally, to include medicated abortions, so that beyond the 2013 Act other state regulations related to abortion procedures apply in full force to the use of mifepristone, as well, described in more detail in GBP's Complaint. Mississippi's restrictions ***fundamentally alter*** who may prescribe GBP's product, where it may be dispensed, the number and type of interactions a patient must have with a provider before it can be prescribed, and additional information provided to patients. The FDA could impose many of these restrictions to ensure safety if, in their view, such restrictions were necessary for safe use of this product and not unduly burdensome on patient access – and the FDA chooses not to.

a claim. Faced with that, Defendant characterizes obstacle preemption as a "narrow doctrine," and resorts to arguing that "it would require an expansion of the law for it to apply in this case." Def's. Mem. at 19. There have been hundreds, maybe thousands, of successful conflict preemption claims, and Defendant fails to explain in what way the doctrine would have to be expanded to fit this case. Indeed, *Wyeth v. Levine,* 555 U.S. 555 (2009), on which Defendant relies heavily, stands for the proposition that when it is impossible for a drug manufacturer to comply with both federal and state labeling requirements, state tort law is preempted. *See also Merck Sharp & Dohme Corp. v. Albrecht,* 587 U.S. —, 139 S. Ct. 1668 (2019). Even with respect to labeling requirements, the Supreme Court acknowledged the possibility that in at least some circumstances, there could be preemption. *See Wyeth,* 555 U.S. at 581 (Breyer, J., concurring) (explaining that the FDA may determine "when labeling requirements serve as a ceiling as well as a floor. And it is possible that such determinations would have pre-emptive effect."). The Court has had no occasion to consider the preemptive effect of the REMS regulations, an entirely separate area of FDA regulation.[8]

Here, by contrast, Congress tasked the FDA with balancing competing interests – patient safety and the benefits of access. The FDA's determination of which restrictions are appropriate for a given drug is both ceiling and floor because the agency is deciding both what to restrict and what not to restrict to strike the necessary balance. Any amount of additional state restriction changes that calculus. Indeed, the Court "recognize[d] that some state-law claims might well

[8] As GBP explained in its Complaint, a REMS goes far beyond just the labeling requirements for a medication, it can include any or all of the following: a medication guide and/or patient package insert; a communication plan; and elements to assure safe usage (*i.e.*, "ETASU"), such as a restricted distribution scheme or special requirements for the administration of the drug. 21 U.S.C. §§ 355-1(e)–(f), Compl. ¶ 31. Congress mandated clear and complete authority to the Secretary to ensure FDA appropriately balances a drug's benefits against its "serious risks" when imposing REMS requirements. *Id.* § 355-1(a)(1), Compl. ¶ 29.

frustrate the achievement of congressional objectives" for the FDA. *Wyeth*, 555 U.S. at 581. Mississippi's draconian restrictions on the use and sale of mifepristone is one such case.

Defendant claims that there is a "strong presumption" that the state's conflicting laws can "coexist" with the federal regulations because the challenged Mississippi laws promote health and safety. Def's. Mem. at 19. Defendant appears to suggest that this presumption indicates that GBP has somehow failed to adequately plead its preemption claim. Despite Mississippi's contention, there is no special "abortion exemption" to the generally applicable rules of preemption (and Defendant has cited no such authority) and an abortion-inducing medication does not give the state an unchallenged ability to choose whether to conflict with federal law and frustrate Congressional intent. As the *Zogenix* Court stated: "Preemption principles have no less heft because health is a matter of 'special concern' to the states." *Zogenix, Inc. v. Patrick*, No. CIV.A. 14-11689-RWZ, 2014 WL 3339610, at *4 (D. Mass. July 8, 2014), *vacated in part,*[9] No. CIV.A. 14-11689-RWZ, 2014 WL 4273251 (D. Mass. Aug. 28, 2014) (citing *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982) (concluding as much with respect to real property law)); *Free v. Bland*, 369 U.S. 663, 666 (1962) ("The relative importance to the State of its own law is not material when there is a conflict with a valid federal law, for the Framers of our Constitution provided that the federal law must prevail."); *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 210, 6 L. Ed. 23 (1824) (state laws passed pursuant to police powers must yield if they conflict with federal law). In any event, as *Zogenix* demonstrates, GBP's conflict preemption claim has been recognized by other cases in similar situations, a clear indication that dismissal for failure to state a claim is not appropriate here.

[9] The preliminary injunction was vacated after the state revised its regulations to remove the conflict with the FDA's regulations.

C. GenBioPro Adequately Pleaded a Valid Dormant Commerce Clause Claim

GBP has also adequately pleaded its dormant Commerce Clause claim. The dormant Commerce Clause holds unconstitutional state action that imposes significant burdens on interstate commerce through inconsistent regulation of activities that are inherently national or require a uniform system of regulation. *Gen. Motors Corp. v. Tracy*, 519 U.S. 278, 298 n.12 (1997); *CTS Corp. v. Dynamics Corp. of Am*., 481 U.S. 69, 88 (1987). State law, even where it appears nondiscriminatory on its face, violates the Commerce Clause if it burdens interstate commerce and the "burden . . . is clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church. Inc*. 397 U.S. 137, 142 (1970); *see also Wood Marine Serv., Inc., v. City of Harahan*, 858 F.2d 1061, 1064-65 (5th Cir. 1988).

GenBioPro's Complaint alleges that (1) GBP's mifepristone tablets move in interstate commerce (Compl. ¶ 7); (2) the prescription drug market operates, inherently, nationwide (Compl. ¶ 90); and (3) by imposing restrictions that not only conflict with the FDA's REMS for mifepristone but that are clearly excessive to any purported benefit, Mississippi law significantly burdens interstate commerce (Compl. ¶¶ 90-92). Defendant does not dispute that GBP's product moves in interstate commerce. Def's. Mem. at 21. What Defendant seems to challenge is whether Mississippi's regulations act as a burden on interstate commerce. But that is not a challenge to be resolved at the motion to dismiss stage. Because GBP has sufficiently pleaded the grounds upon which its Dormant Commerce Claim lies, Defendant's motion to dismiss GBP's dormant Commerce Clause claim should be denied.

CONCLUSION

For the foregoing reasons, Defendant's Motion to Dismiss should be denied.

Dated: November 20, 2020

Respectfully submitted,

GENBIOPRO, INC.

By Its Attorneys,

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CERTIFICATE OF SERVICE

I certify that I have this day electronically filed the foregoing with the Clerk of the Court using the ECF system which served a copy upon all counsel of record who have registered with that system.

This the 20th day of November, 2020.

/s/ J. Carter Thompson, Jr.
J. CARTER THOMPSON, JR.